S/N 10/723,254 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	David J. Yonce et al.	Examiner: Frances Oropeza
Serial No.:	10/723,254	Group Art Unit: 3766
Filed:	November 26, 2003	Docket No.: 279.628US1
Customer No.:	45458	Confirmation No.: 6063
Title:	MORPHOLOGY-BASED DIAGNOSTIC MONITORING OF ELECTROGRAMS BY IMPLANTABLE CARDIAC DEVICE	

RESPONSE TO NOTICE OF NON-COMPLIANT APPEAL BRIEF

Appeal - Brief - Patents
Commissioner for Patents
P.O. Box 1450
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This responds to the Notice of Non-Compliant Appeal Brief mailed on February 26, 2009. In compliance with 37 C.F.R. 1.121, Appellants have corrected and hereby resubmit the Section V and Section VII of the previously submitted Appeal Brief filed January 21, 2009.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claims 1 and 11 recite systems for recording and presenting electrophysiological data. The claims are as set forth below, to which have been added in parentheses the reference numerals used in the specification and page/line numbers from the specification.

INDEPENDENT CLAIM 1

1. A system for recording and presenting electrophysiological data, comprising:

an implantable cardiac device having a first sensing channel (e.g., 43a ,43b, and 41 as described on page 8, lines 4-22) for sensing cardiac electrical activity and generating electrogram signals;

wherein a controller (10, 12 as described on page 7, lines 22-30) of the implantable cardiac device is programmed to:

record electrograms over a specified long-term period of time (as described on page 10, lines 18-25),

generate representative electrograms for each of a plurality of discrete time intervals within the specified long-term period of time (as described on page 11, lines 3-10), and

compute the representative electrogram for each discrete time interval as a time average of electrograms recorded during the discrete time interval only when the patient's heart rate is within a specified range (as described on page 11, lines 1-3); and,

an external programmer (300) configured to download representative electrograms from the implantable device and display an aggregate of representative electrograms in graphical form as indexed by time (as described on page 10, lines 13-16 and on page 11, lines 11-15).

INDEPENDENT CLAIM 11

11. A system for recording and presenting electrophysiological data, comprising:

an implantable cardiac device having a first sensing channel (e.g., 43a ,43b, and 41 as described on page 8, lines 4-22) for sensing cardiac electrical activity and generating electrogram signals;

wherein a controller (10, 12 as described on page 7, lines 22-30) of the implantable cardiac device is programmed to:

record electrograms over a specified long-term period of time (as described on page 12, lines 1-3),

generate representative electrograms for each of a plurality of heart rate ranges during the specified long-term period of time by computing each representative electrogram for a particular heart rate range as a time average of a plurality of electrograms recorded when a patient's heart rate is within the particular heart rate range (as described on page 12, lines 3-8), and

compute the representative electrogram for a particular heart rate range from one or more electrograms recorded only when the patient's heart rate is within the particular heart rate range (as described on page 12, lines 3-8); and,

an external programmer (300) configured to download representative electrograms from the implantable device and display an aggregate of representative electrograms in graphical form as indexed by the plurality of heart rate ranges (as described on page 10, lines 13-16 and on page 12, lines 9-20).

The subject matter recited above relates to the aggregate display of what are referred to as representative electrograms. An electrogram is a waveform that represents the temporal course of the depolarization and repolarization of the heart as it beats. The term "electrogram" is usually used to refer to such waveforms that are recorded using internal electrodes, as opposed to an electrocardiogram (ECG) that is recorded with surface electrodes. Some references, however, use the term electrogram to refer to a waveform recorded with either surface or internal electrodes. In any event, electrograms reveal a great deal of information to a clinician and can be used to diagnose many different pathologies. The present application is concerned with presenting electrophysiological information reflective of a patient's condition to a clinician in a visually informative way. The claimed subject matter involves the collection of electrograms over some long-term period of time, the computation of a plurality of representative electrograms, and the aggregate display of the representative electrograms to enable the clinician to readily ascertain morphology differences between them. As explained below, the representative electrograms may be computed so as to reflect changes in electrogram

morphology over time or to reflect how electrogram morphology changes as the patient's heart rate varies.

One aspect of electrogram morphology that may be useful for a clinician to assess is how the morphology may be changing over time. Morphological features that, by themselves, may either be ambiguous or of little significance, may nevertheless be significant if such features are part of a trend or show other types of variation over time. Claim 1 describes a system that collects electrograms over a specified long-term period of time and then generates representative electrograms for each of a plurality of discrete time intervals within the specified long-term period of time. In order to eliminate the natural variability from the electrogram data, an averaging process is used so that he representative electrograms are computed as an average of electrograms recorded during a particular discrete time interval. (Averaging, in this context, refers to simple averaging of corresponding waveform amplitudes to construct an average waveform.) For example, the discrete time interval may be a day so that daily averages of recorded electrograms are obtained for some long-term period of time (e.g., a month). As noted above, electrogram morphology also changes as the heart rate varies. In order to control for this type of variation and eliminate it from the data, the representative electrograms for each discrete time interval are computed from electrograms recorded only when the heart rate is within a specified range. Each of the representative electrograms (daily average electrogram waveforms, for example) then represents the typical electrogram that the patient exhibited when the heart rate was within the specified range. The system is configured to simultaneously display the representative electrograms in aggregate fashion as indexed by time to enable a clinician to readily ascertain by visual inspection how the electrogram morphology is either changing or remaining stable over the long-term time period.

In the system recited by claim 1, the variation in electrogram waveform morphology with respect to heart rate is essentially regarded as noise that is to be averaged out of the representative electrograms. Such morphological variation with respect to heart rate, however, may itself be revealing of useful information to a clinician. For example, a patient may exhibit a Q-T interval (i.e., the interval between ventricular depolarization and repolarization) that is within the normal range for any given heart rate but exhibit changes in the Q-T interval as the heart rate varies that are not normal. Claim 11 recites a system that records electrograms over a

specified long-term period of time and then generates representative electrograms for each of a plurality of heart rate ranges. Each representative electrogram for a particular heart rate range is computed as a time average of electrograms recorded only when a patient's heart rate is within the particular heart rate range. That is, each representative electrogram is intended to represent a typical waveform morphology for a particular heart rate range. The system is configured to simultaneously display the representative electrograms for each of the heart rate ranges in aggregate fashion as indexed by heart rate. The aggregate display enables a clinician to readily assess how the patient's electrogram morphology changes with heart rate.

7. ARGUMENT

§102 Rejection of the Claims

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. M.P.E.P § 2131. To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter. PPG Industries, Inc. V. Guardian Industries Corp., 75 F.3d 1558, 37 USPQ2d 1618 (Fed. Cir. 1996). The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1, 4, 5, 7, 9-11 and 14-16 were rejected under 35 USC § 102(e) as being anticipated by Levine. The Final Office Action states:

> Levine et al. disclose a method and apparatus for displaying information comprising an implantable device (100) the implantable device comprising a first sensing channel (82 or 84) and a controller (60). The method and apparatus further comprise an external programmer (102) including a display (video display (214)and printer (236)) to show graphical data (waveform and histogram). The electrocardiogram data is compiled with respect to heart rate in specific ranges and over a specified long-term period of time. Events are time stamped/ marked (abstract; figures 2,3, 5, 8-1 1B; column 5, lines 33-45; column 7, lines 7-16; column 8, lines 29-33 and 48-52; column 9, lines 1-12; column 10, lines 60-62; column 12, lines 53-54; column 13, lines 59-61; column 14, lines 16-18, 3 1-34; column 15, lines 5-12; column 15, line 67 - column 16, line 3; column 16, lines 17-1 9).

The Office Action then goes on to say:

> As to claims 1, 9 and 11, Levine et al. incorporate by reference Snell et al. (U.S. Patent No. 5,431,691) (column 2, lines 18-28) who disclose recording data continuously for discrete time intervals and determining the average for each of the discrete time intervals (column 17, lines 60-66; column 22, lines 5-16). Levine et al. disclose displaying graphical information such as an electrogram from a collection of data (column 15, lines 53-56; column 16, lines 48-51), disclose gathering heart rate information based on ranges of

> heart rate (column 14, lines 31-34) and discloses the data being recorded over a relatively long period of time (column 14, lines 60-63), hence Levine et al. and Snell et al. are read to teach computing the representative electrogram for each discrete time interval as a time average of electrograms recorded during the discrete time interval when the heart rate is in a specific range.

Appellant believes that the Final Office Action as quoted above erroneously characterizes what is disclosed by the Levine and Snell references and has not made a *prima facie* showing of anticipation. As best understood, the Levine reference describes a system for collecting electrograms and cardiac event data from multiple cardiac locations and then displaying the electrograms or event data in a location-specific manner. For example, Levine describes collecting and displaying electrograms from each of the four heart chambers. The Snell reference describes a system for recording and displaying pacing events over a period of time. Neither the Levine nor the Snell reference describe the following elements of the system recited by claim 1: 1) a system component configured to compute an average electrogram from a plurality of electrograms taken over some period of time (i.e., over the discrete time interval), 2) a system component configured to compute a plurality of average electrograms for a plurality of discrete time intervals, referred to as representative electrograms, or 3) a system component configured to aggregately display a plurality of electrograms, each of which have been recorded different periods of time (i.e., the representative electrograms that represent the different discrete time intervals). The Levine reference, at col. 15, lines 64-66, does describe averaging electrograms recorded from different locations, and does refer to the time stamping of events. Appellant finds no description of averaging electrograms recorded at different times, however, and further finds no description of simultaneously displaying electrograms recorded at different times, whether averaged or not, in graphical form as indexed by time. The Snell reference does not describe displaying electrograms in any form, and contains no discussion relating to the computation of any kind of average electrogram.

Neither the Levine nor the Snell reference describes the following elements as recited by claim 11: 1) a system component for computing an average of electrograms recorded while the heart rate is within a particular range, 2) a system component for computing a plurality of representative electrograms where each such representative electrogram is an average of

electrograms recorded while the heart rate is within a different heart rate range, or 3) a system component configured to simultaneously display a plurality of electrograms, whether averaged or not, recorded while the heart rate is within different heart rate ranges and to index the displayed electrograms by heart rate. The only mention of the collection and display of data with respect to different heart rates that Appellant finds in Levine is at col. 14, lines 24-34, where the reference describes using different bins for counting particular cardiac events at different heart rate ranges in order to generate a histogram of such events as a function of heart rate. Such a histogram of cardiac events, however, is in no way similar to the recording of *electrograms* at different heart rate ranges and aggregately displaying such electrograms.

For the reasons state above, Appellant believes that claims 1 and 11, as well as the claims depending therefrom, are clearly not anticipated by the Levine reference. Applicant also finds nothing in the cited references that either suggests or would otherwise lead one of ordinary skill in the art to arrive at the claimed subject matter.

§103 Rejection of the Claims

Applicant further believes that the recitations of the dependent claims, such as using different shades or colors for the different representative electrograms as recited by claims 8 and 17, are neither taught nor suggested by the cited references in the context of their combination with the subject matter of either claim 1 or claim 11. As best understood, the Palmer reference describes the use of color coding for signifying different amplitude values of displayed variables. Applicant does not believe that such a color coding scheme is in any way similar to the use of different colors for displaying representative electrograms in order to indicate the time period or heart rate range represented by the electrograms as recited by claims 8 and 17.

CONCLUSION

In response to the Notice of Non-Compliant Amendment and in accordance with 37 C.F.R. 1.121, Appellants have corrected and resubmitted Section V and Section VII of the response for the Examiner's consideration.

Appellants respectfully submit that the Examiner withdraw the non-compliant status and examine the response as appropriate.

The Examiner is invited to telephone Applicants' representative at (847) 432-7302 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account 19-0743.

Respectfully submitted,

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Date March 30, 2009 By / J. Kevin Parker /

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Appeal - Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 30th day of March, 2009.

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